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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSCU-128/00US 027060-2694	1401
58249 7590 06/19/2009 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001				
EXAMINER				
PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
06/19/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/935,487

Applicant(s)

RIOUX ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 8, 17-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 17-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/6/09 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,17-20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beyar et al. (5372600) in view of Mikus et al. (5830179) and Goicoechea (6010530). Beyar et al. disclose a stent for use within a body lumen, col. 3, lines 16-18. It can be seen (Fig. 3) that the stent **17** is a unitarily formed coil segment defining a lumen there through and includes distal, middle and proximal portions. Beyar et al. also discloses the distance between a coil winding of a stent placed in a vessel is at least about 0.5mm, col. 7, lines 5-7. Beyar discloses the coil segment being extendable lengthwise from a first length to an extended length and being compressible lengthwise from the extended length, col. 4, lines 18-38. It can also be seen (Fig. 6) there is at least one hook **16** on proximal and distal portions to permit connection to a delivery system **12**. Beyar additionally states the structures for attachment can be hooks at both the

proximal and distal ends of the coil body for connection to a delivery system, col. 7, lines 8-17.

Beyar et al. does disclose (col. 7, lines 18,19) varying diameter for the stent but does not explicitly state the stent having each of the distal and proximal portions including a diameter greater than a diameter of the middle portion. Beyar also discloses (col. 6, line 60) coating layers of silicone can be placed on the wire, but does not explicitly state it is placed such that the polymer material encapsulates the coil segment and disposed between the spaced windings of the wound element to form an imperforate flexible webbing. Mikus et al. teach (Fig. 7) a stent in the form of a coil segment with a middle portion **35** and proximal and distal ends **28,29**. Mikus additionally teaches that the middle portion has a diameter less than the proximal and distal ends which are flared **30,31**, col. 6, lines 36-39. Goicoechea teaches (Figs. 1,2) a stent **11** which has been encapsulated by a flexible polymer material **12** that encapsulates the coil segment and has an outer **14** and inner layer **15**. It would have been obvious to one of ordinary skill in the art to incorporate flared ends as taught by Mikus et al. with the coil of Beyar et al. such that it enables the stent to be better anchored when used in a vessel such as the prostatic urethra. Additionally, it would have been further obvious to one of ordinary skill in the art to incorporate a flexible polymer webbing that encapsulates the stent as taught by Goicoechea with the coil of Beyar et al. as modified with Mikus such that it holds a radiopaque material for enhance visibility, see Goicoechea, col. 4, lines 66,67. Regarding claims 2,3, Beyar discloses the wire is biocompatible and can be stainless steel, col. 6, lines 52-60. With respect to claim 4, Beyar additionally disclose (col. 6, lines 64-66) the wire cross-section area is in the range of $0.0079 - 0.0071\text{mm}^2$. With respect to claims 20,22, Beyar discloses the stent is placed in the prostatic urethra before

the sphincter, col. 7, lines 62-65 and thus has sufficient strength to maintain an open passageway.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beyar et al. '600 in view of Mikus et al. '179 and Goicoechea '530 as applied to claim 1 and further in view of Hachtman et al. (5645559). Beyar et al. in view of Mikus and Goicoechea is explained *supra*. However, Beyar as modified with Mikus and Goicoechea do not disclose the silicone is a *low durometer* silicone within the range of 0-60D. Hachtman et al. teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Beyar et al. wire stent modified with Mikus and Goicoechea such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Response to Arguments

Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738